4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 131**

**[Docket No. FDA-2000-P-0126 (formerly Docket No. 2000P-0658)]**

# International Dairy Foods Association: Response to the Objections and Requests for a Public Hearing on the Final Rule to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and Amend the Standard for Yogurt

**AGENCY**: Food and Drug Administration, HHS.

**ACTION**: Final order; response to objections and denial of public hearing requests; removal of administrative stay; final amendment.

**SUMMARY**: The Food and Drug Administration (FDA or we) published a final rule entitled "Milk and Cream Products and Yogurt Products; Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt," on June 11, 2021 (the 2021 final rule). The International Dairy Foods Association (IDFA) objected to the final rule's provision that yogurt have either a titratable acidity of not less than 0.7 percent, expressed as lactic acid, or a pH of 4.6 or lower before the addition of bulky flavoring ingredients. We are denying IDFA's request for a public hearing with respect to this objection and are issuing a final order to modify the final rule's provision with respect to both pH and titratable acidity.

**DATES**: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The administrative stay is lifted [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The compliance date is [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES**: You may submit objections and requests for a hearing on new provisions added by this response to objections as follows. Please note that late, untimely filed objections will not be considered. The https://www.regulations.gov electronic filing system will accept comments

until 11:59 p.m. Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*Electronic Submissions*

Submit electronic objections in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on https://www.regulations.gov.
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions*: All submissions received must include the Docket No. FDA-2000-P-0126 for "International Dairy Foods Association: Response to the Objections and Denial of the Requests for a Public Hearing on the Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt." Received objections, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

*Docket*: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT**: Andrea Krause, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371, or Holli Kubicki, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

**SUPPLEMENTARY INFORMATION**:

## I. Background

Section 401 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 341) directs the Secretary of Health and Human Services (Secretary) to issue regulations fixing and establishing for any food a reasonable definition and standard of identity whenever, in the judgment of the Secretary, such action will promote honesty and fair dealing in the interest of consumers. Under section 701(e)(1) of the FD&C Act (21 U.S.C. 371(e)(1)), any action for the amendment or repeal of any definition and standard of identity under section 401 of the FD&C Act for any dairy product (e.g., yogurt) must begin with a proposal made either by FDA under our own initiative or by petition of any interested persons.

In the *Federal Register* of June 11, 2021 (86 FR 31117), we issued a final rule (the 2021 final rule) amending the definition and standard of identity for yogurt ((§ 131.200) (21 CFR 131.200)) and revoking the definitions and standards of identity for lowfat yogurt (21 CFR 131.203) and nonfat yogurt (21 CFR 131.206). This action was in response, in part, to a citizen petition submitted by the National Yogurt Association. The final rule modernized the yogurt

standard to allow for technological advances while promoting honesty and fair dealing in the interest of consumers.

The preamble to the final rule stated that the effective date of the final rule would be July 12, 2021, except as to any provisions that may be stayed by the filing of proper objections (86 FR 31117 at 31136). Pursuant to section 701(e) of the FD&C Act, the final rule notified persons who would be adversely affected by the final rule that they could file objections, specifying with particularity the provisions of the final rule deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. We gave interested persons until July 12, 2021, to file objections and request a hearing on the final rule.

The IDFA timely filed objections and requested a hearing with respect to several provisions in the final rule (see Objections and Request for Hearings submitted by Michael Dykes, DVM (IDFA objection), President and Chief Executive Officer, IDFA, dated July 12, 2021, to the Dockets Management Staff, Food and Drug Administration (Comment ID FDA-2000-P-0126-0109). Section 701(e)(2) of the FD&C Act provides that, until final action is taken by the Secretary, the filing of objections operates to stay the effectiveness of those provisions to which the objections are made.

In the *Federal Register* of March 23, 2022 (87 FR 16394) we issued a final rule providing clarification on which provisions of the 2021 final rule were stayed and which requirements of the previous final rule that we issued in 1981 (46 FR 9924) (1981 final rule) are in effect pending final action under section 701(e) of the FD&C Act. In the *Federal Register* of December 15, 2022 (87 FR 76559), we published a final rule (2022 final rule) denying IDFA's requests for a hearing with respect to all but one of their objections. The 2022 final rule provided modifications to certain provisions in the final rule and announced that the stay of effectiveness of provisions for which hearings were denied was lifted. We did not address IDFA's objection and request for a hearing on the provision in § 131.200(a) that yogurt have either a titratable acidity of not less than 0.7 percent, expressed as lactic acid, or a pH of 4.6 or

lower before the addition of bulky flavoring ingredients (hereinafter referred to as "the acidity requirement"). We addressed this objection and request for a hearing in a proposed order, which we sent to IDFA under § 12.24(d) (21 CFR 12.24(d)) and posted to the docket for public review (Document ID FDA-2000-P-0126-0129). FDA regulations provide that after the Commissioner serves a proposed order denying a hearing, a person has 30 days after receipt of the proposed order to demonstrate that the submission justifies a hearing (§ 12.24(d)). FDA did not receive any response to the proposed order, and we are now issuing a final order denying IDFA's request for a hearing on the acidity requirement and amending the 2021 final rule with respect to this requirement.

## II. Objection and Request for a Hearing on the Acidity Requirement

The acidity requirement in § 131.200(a) of the 2021 final rule is comprised of two options: yogurt must either have a minimum titratable acidity of 0.7 percent or a maximum pH of 4.6 before bulky flavoring ingredients are added. IDFA objected to both of these options, asserting that they are not practical and do not reflect consumer taste preferences or current industry practice for yogurt manufacturing. IDFA stated that the requirement will not promote honesty and fair dealing in the interest of consumers. IDFA asserted that the requirement should be a titratable acidity of not less than 0.6 percent, expressed as lactic acid, measured in the white mass of the yogurt, or a pH of 4.6 or lower measured in the finished product within 24 hours after filling. IDFA requested a hearing on the following issues: (1) whether a requirement that titratable acidity or pH be reached prior to the addition of bulky flavors in the manufacturing process is consistent with the basic nature and essential characteristics of yogurt; (2) whether a requirement that prohibits yogurt from being filled at a pH of 4.8 or less and reaching a pH of 4.6 or below within 24 hours after filling is consistent with the basic nature and essential characteristics of yogurt; and (3) whether a minimum titratable acidity requirement of 0.7 percent is in the interest of consumers and necessary to maintaining the basic nature and essential characteristics of yogurt.

We are denying IDFA's request for a hearing with respect to both the titratable acidity minimum and pH maximum under § 12.24(b)(1). We are modifying the 2021 final rule with respect to the pH maximum in accordance with IDFA's request, and we are modifying the 2021 final rule to eliminate the option of complying with a minimum titratable acidity.

*A. Denial of Request for a Hearing on Maximum pH Option*

With respect to the maximum pH option, IDFA objected to requiring the pH to be reached prior to the addition of bulky flavoring ingredients and requiring the pH of 4.6 in the white mass of the yogurt prior to filling. IDFA explained that modifications made to the Grade "A" Pasteurized Milk Ordinance (PMO) in 2007 exempted yogurt from certain cooling requirements based on an initial pH of 4.8 or below at filling and with the product reaching a pH of 4.6 or below within 24 hours of filling. (The PMO is a model regulation intended to help States and municipalities initiate and maintain effective programs for the prevention of milk-borne disease. State and local milk control agencies can adopt the PMO.) IDFA stated that bulky flavoring ingredients such as fruits and fruit preparations are added before achieving the target pH (pH 4.6) and prior to filling. Before accepting this change in the PMO, FDA and the National Conference on Interstate Milk Shipments reviewed pathogen challenge study data regarding this manufacturing practice and concluded that exempting yogurt from the cooling requirements of the PMO is safe when this specific practice is followed. In its objection, IDFA also asserted that such products (manufactured with an initial pH of 4.8 or below at filling and with the product reaching a pH of 4.6 or below within 24 hours of filling) have been on the market for many years and accepted by consumers without deviating from the basic nature and essential characteristics of yogurt and maintaining honesty and fair dealing in the interest of consumer.

We agree that the key safety control measure for finished yogurt is pH and, secondarily, temperature control (i.e., refrigeration). Also, the pH process described in the PMO for yogurt contains other factors that contribute to preventing growth of different kinds of

microorganisms. For example, the relatively rapid pH drop during fermentation (and the final pH achieved) is the primary control measure for pathogenic sporeformers in yogurt. Microbiological safety by acids relies on the pH value of the food, and pH is a parameter that is easily measurable. The pH values that inhibit growth of microbial pathogens are generally well-known by food safety professionals and easily found in the scientific literature.

Based on all available information, including the information presented in the objections from IDFA, FDA is amending the yogurt standard regarding the acidity requirement in § 131.200(a). We are revising § 131.200(a) as requested by IDFA, and consistent with the PMO, to require a pH of 4.6 or lower measured on the finished product within 24 hours after filling. The finished product refers to the yogurt white mass after the addition of bulky flavors. If a bulky flavor (e.g., fruit pieces) added to yogurt increases the pH, the pH must be 4.6 or lower after the product has had time to equilibrate. This requirement will ensure the safety of yogurt, while maintaining its basic nature and essential characteristics.

This amendment is consistent with IDFA's proposed modification to the maximum pH option. Therefore, we are denying IDFA's request for a hearing with respect to the maximum pH option under § 12.24(b)(1) because there is not a genuine and substantial issue of fact for resolution at a hearing.

*B. Denial of Request for a Hearing on the Minimum Titratable Acidity Option*

IDFA objected to the minimum titratable acidity of 0.7 percent and requested that we modify the 2021 final rule to provide for a minimum titratable acidity of 0.6 percent. IDFA explained that a minimum titratable acidity of 0.6 percent is necessary to produce certain low calorie yogurt products that meet consumer expectations of a delicate and less tart yogurt taste that is not too acidic or sour. IDFA stated that if a titratable acidity requirement of 0.7 percent is imposed, some manufacturers may need to adjust formulations and add sugars to counteract the acidity and deliver a product that meets consumer expectations and preferences. IDFA

emphasized that a minimum titratable acidity of 0.6 percent would provide manufacturers with needed flexibility.

Because we are modifying the maximum pH option consistent with the pH specifications in the PMO, which States have adopted, manufacturers are already required to comply with the maximum pH option. Therefore, the minimum titratable acidity option in the 2021 final rule, whether set at 0.7 percent or 0.6 percent, is superfluous and would not provide flexibility to manufacturers. So long as manufacturers comply with the maximum pH option, they may manufacture yogurt with a titratable acidity of 0.6 percent and can accommodate consumer expectations and preferences without reformulating their products. We note that the maximum pH option we are finalizing has been in effect in States for several years and, by itself, appears sufficient to ensure the safety of yogurt products. With the elimination of the titratable acidity option, we are also removing § 131.200(e)(1)(iii) *Methods of analysis, Titratable acidity* and the corresponding method incorporated by reference in § 131.200(i)(1)(i).

We are denying IDFA's request for a hearing on whether a minimum titratable acidity requirement of 0.7 percent is in the interest of consumers and necessary to maintaining the basic nature and essential characteristics of yogurt. Given our modification to the maximum pH option, a minimum titratable acidity option is unnecessary, and we do not believe there is a genuine and substantial issue of fact for resolution at a hearing (§ 12.24(b)(1)).

## III. Conclusions

For the reasons explained above, we are denying IDFA's request for a hearing with respect to both the maximum pH option and the minimum titratable acidity option under § 12.24(b)(1). We are modifying the acidity requirement in § 131.200(a) in the 2021 final rule to eliminate the minimum titratable acidity option and require that yogurt have a pH of 4.6 or lower measured on the finished product within 24 hours after filling.

This final order is being issued after following the process provided under § 12.24(d). Objections to or requests for hearing on the modification and revocation may be submitted

under 21 CFR 12.20 through 12.22 in accordance with 21 CFR 12.26. The stay of effectiveness with respect to the acidity requirement is lifted upon publication of this final order in the *Federal Register*.

## IV. Reference

The following reference is on display at the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at https://www.regulations.gov. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration. Grade "A" Pasteurized Milk Ordinance. 2019. Available at: https://ncims.org/wp-content/uploads/2020/07/2019-PMO.pdf (last accessed February 6, 2023).

**List of Subjects in 21 CFR Part 131**

Cream, Food grades and standards, Milk, Yogurt.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 131 is amended as follows:

**PART 131--MILK AND CREAM**

1. The authority citation for part 131 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

2. In § 131.200:

a. Revise the fourth sentence of paragraph (a);

b. Remove paragraphs (e)(1)(iii) and (i)(1)(i); and

c. Redesignate paragraphs (i)(1)(ii) and (iii) as paragraphs (i)(1)(i) and (ii).

The revision reads as follows:

**§ 131.200 Yogurt.**

(a) * * * Yogurt contains not less than 3.25 percent milkfat, except as provided for in paragraph (g) of this section, and not less than 8.25 percent milk solids not fat and has a pH of 4.6 or lower measured on the finished product within 24 hours after filling.* * *

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Dated: April 6, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2023-07723 Filed: 4/13/2023 8:45 am; Publication Date: 4/14/2023]